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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,189	04/16/2004	Patrick Scholten	P10670.01	9794
27581	7590	10/31/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			ALTER, ALYSSA M	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/826,189	Applicant(s) SCHOLTEN ET AL	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see 4, filed October 12, 2005, with respect to the rejection(s) of claim(s) 1-48 under 35 U.S.C. 102(b) and 103(a) have been fully considered and are persuasive, however the Double Patenting rejection still stands. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Florio et al. (US Patent Publication 20010049542 A1).

Double Patenting

Claims 1-54 of this application conflict with claims 1-48 of Application No. 10/424,538 (US Patent Publication 20040215276 A1). 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in

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scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

1. Claims 1-4, 8, 12, 14, 16-17, 22-23, 25-32, 36, 40, 42, 44-45, 50-51 and 53-54 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4, 6, 8, 10, 12-14, 16-17, 20-27, 29, 31, 33, 35-36, 39-40 and 43-44 of copending Application No. 10/424,538 (US Patent Publication 20040215276 A1). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

2. Claims 5-7, 9-11, 13, 15, 18-21, 24, 33-35, 37-39, 41, 43, 46-49 and 52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5, 7, 9, 11, 15, 18-19, 28, 30, 32, 34, 37-38, 41-42 and 45-48 of copending Application No. 10/424,538 (US Patent Publication 20040215276 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both disclose the comparison of a sensed morphological characteristic to a threshold value.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4, 8, 12, 14, 18, 22-32, 36, 38, 40, 42, 46, and 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Florio et al. (US Patent Publication 20010049542 A1). Florio et al. discloses a system for detecting capture during multi-chamber stimulation by "sensing a composite cardiac signal on a single sense channel that has, inherent in it, characteristics that permit the detection of non-capture, single-chamber capture, and bi-chamber capture"(page 3, paragraph 25).

As to claims 4, 8, 12, 14, 18, 22, 32, 36, 40, 42, 46 and 50, Florio et al. further discloses on page 8, paragraphs 91-102, the microprocessor 60 (FIG. 2) processes the intracardiac electrogram (IEGM) waveforms and detects a number of parameters or characteristics defining the IEGM morphology, including a template representation of the overall IEGM waveform, peak negative amplitude, peak positive amplitude, positive slope, negative slope, positive integral, negative integral, a number of inflection points or zero crossings, time duration (width) of depolarizations, time interval between the ventricular stimulation pulse and any subsequently detected events and/or time interval between detected events. The examiner considers the sensed morphology characteristics of peak negative amplitude to be minimum voltage of the sensed signal, the positive slope to be the maximum slope of the sensed signal and the negative slope to be the minimum slope of the sensed signal.

As to claims 2-3, 23, 25-26, 30-31, 51 and 54, "One or more of these IEGM characteristics are then used by the method of the present invention, as it will be described below, in order to distinguish between single-chamber capture, bi-ventricular capture, or complete loss of capture, based on comparisons made between an acquired

IEGM during normal stimulation device operation and the known characteristics of the IEGM during the three capture situations. In a preferred embodiment, IEGM characteristics representing the typical morphologies of the IEGM during (1) single-chamber capture, and (2) bi-ventricular capture, are stored in memory 94 (FIG. 2).

These IEGM characteristics are acquired and stored during threshold testing performed at the time of device implant or at a follow-up office visit. During threshold testing, the ventricular stimulation pulse amplitude is progressively increased in small steps until single-chamber capture is recognized on the IEGM display. Once single-chamber capture is verified, the IEGM waveform is stored in memory as the single-chamber capture template”(page 8, paragraphs 103-104). The examiner considers these known characteristics, or typical morphologies, to be criteria to which the characteristics are compared with in order to determine capture.

As to claim 24-25 and 52-53, figure 2 displays the analog-to-digital converter 90, atrial sensing circuit 82 and the ventricular sensing circuit 84. “Each of the atrial sensing circuit 82 or the ventricular sensing circuit 84 preferably employs one or more low power, precision amplifiers with programmable gain and/or automatic gain control, bandpass filtering, and a threshold detection circuit, to selectively sense the cardiac signal of interest” (page 5, paragraph 60). Since the cardiac signal is subjected to bandpass filtering, the examiner considers the sensed signal to be a filtered sensed signal.

As to claims 26-29, figure 1 displays a pulse generator 10 connected to leads 30, 20 and 24 with electrodes disposed on the distal end.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 5, 9, 13, 15, 19, 33, 37, 41, 43, and 47 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Florio et al. (US Patent Publication 20010049542 A1). Florio et al. discloses a system for detecting capture during multi-chamber stimulation by comparing morphological characteristics of the sensed signal to stored typical morphological characteristics or criteria. These criteria or typical morphologies inherently include a range.

In the alternative, Florio et al. discloses the claimed invention except for the range of criteria or typical morphologies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a range of criteria or typical morphologies, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a range for the criteria or typical morphologies, since a range would facilitate a tolerance or margin of error in the comparison of the sensed signal morphology to the typical morphology.

2. Claims 6-7, 10-11, 16-17, 20-21, 34-35, 38-39, 44-45 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable modified Florio et al. (US Patent Publication 20010049542 A1) as applied to claims 5, 9, 13, 15, 19, 33, 37, 41, 43, and 47 above, in view of Meyer et al. (US 20040082975 A1). Florio et al. discloses the claimed invention except for the time of minimum slope, maximum slope, minimum voltage and maximum voltage of the sensed signal. Meyer et al. teaches that it is known to time intervals between cardiac signal features, specifically timing of local maxima or minima of the cardiac signal and the rise time and/or fall times of the cardiac signal as set forth on page 6, lines 69, for the purpose of determining capture. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the morphology characteristics or criteria as taught by Florio et al. with the features as taught by Meyer et al., since such a modification would include additional features, of morphological characteristics or criteria, to further enables the detection of capture.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Kroll (US Patent Publication 20010049543 A1) discloses a method and apparatus for biventricular stimulation and capture monitoring.
2. Bradley (US Patent Publication 20030050671 A1) discloses a method and device for enhanced capture tracking by discrimination of fusion beats.

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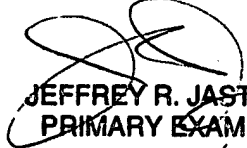
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Alyssa M Alter
Examiner
Art Unit 3762

AT


JEFFREY R. JASTRZAB
PRIMARY EXAMINER
10/29/05